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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,596	02/19/2002	Ronald W. Mink	030793-036100	2706

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NIXON PEABODY, LLP  
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WASHINGTON, DC 20004-2128

EXAMINER
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NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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01/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/076,596

Applicant(s)

MINK ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 53-55 and 57-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 53-55, 57-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2007 has been entered.
2. Claims 1, 53-55 and 57-71 are pending.
3. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and arguments.

### *Claim Rejections - 35 USC § 112, first paragraph*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 53-55 and 57-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 67 have been amended to recite a blocking pad that is disposed within a housing, and is in *planar flow communication* with the capillary matrix. These claims have also been amended to recite that the lateral flow chromatography strip within the housing is in *planar flow communication* with the capillary matrix.

These amendments do not have support in the specification as originally filed. Applicant points to several locations in the specification where support is allegedly found, however, none of these locations recites a blocking pad or a lateral flow chromatography strip in *planar flow communication* with the capillary matrix. Arguments presented in support of this amendment are directed to a limitation where the capillary matrix itself, provides a *planar* surface for insertion into the oral cavity. No where in the specification is there are recitations that the capillary matrix is in *planar flow communication* with the chromatography strip or the blocking matrix.

Claims 1 and 67 are also not supported by the specification with respect to the recitation of a "*non-absorbing*" capillary matrix. The specification at page 13, lines 10-11 recites a capillary matrix that is *essentially non-absorbing*, and at page 21, lines 16-18 recite a capillary matrix that is an *absorbant surface* for uptake of oral fluid. No where in the specification is there a recitation of a capillary matrix that is "non-absorbing".

*Claim Rejections - 35 USC § 112, second paragraph*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57-59 are indefinite because they recites the intended use of the device and do not recite a positive limitation of the device itself, i.e. these claims do not recite the specific reagents that would be required to detect the various analytes.

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1 and 53-55 and 57-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over May (US 5,622,871) in view of Schlipfenbacher (US 5,160,486).

May discloses a device comprising a housing (500) and a strip (506, 510), the strip comprising a collection strip (506) in fluid communication with a lateral flow assay strip (510), wherein the lateral flow assay strip (510) is contained substantially within the

housing, contains at least one blocking agent or buffer (see col. 16 line 67 to col. 17 line 40), contains at least one reagent used to detect the presence or absence of an antibody (see col. 16, lines 59-65), contains one or more zones that indicate the presence or absence of the antibody (see col. 19, lines 57-65). The collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a source to the assay strip (see col. 18, lines 35-40). May specifically teaches that the sample receiving member can be made from any bibulous, porous or fibrous material capable of absorbing liquid rapidly. May teaches porous plastic material such as polypropylene, polyethylene, polyvinylidene fluoride, ethylene vinylacetate, etc. May also teaches treating the member with a surface active agent to enhance its ability to take up and deliver a moist sample rapidly and efficiently. See column 4, lines 43-57. May specifically teaches that materials such as used in the nibs of fibre tipped pens are *particularly* suitable and such materials can be shaped or extruded in a variety of lengths and cross-section as appropriate. See column 4, lines 59-63. Regarding claim 61, the collection strip protrudes from the housing and is a paddle-shape (see Figs. 8 and 9). The lateral flow assay strip is an immunochromatography strip (see col. 15, lines 4-34). The reagent is a binding partner that bears a detectable label (see col. 15, line 35 to col. 17 line 15). Claims 57-59 fail to further structurally limit the claimed device and instead related to analytes which are not part of the device. These claims discuss analytes, but do not relate the discussion of the analytes to the claimed device. However, May does teach

the detection of hormones such as LH and hCG, bacterial agents such as streptococcus and Chlamydia, as well as steroids and drugs. See column 9, lines 14-25. Regarding claims 68 and 69, May ('871) discloses a kit comprising the device discussed above and separately a buffer or reagent (see col. 4, lines 38-42).

May differs from the instant invention in failing to specifically teach a separate blocking strip and a conjugate strip between the collection strip and assay strip,

Schlipfenbacher ('486) teaches providing a blocking strip (23) containing a buffer and a conjugate strip (24) between a collection strip and an assay strip. See column 8, lines 23-31. The reagents in the blocking strip 23 comprise sodium phosphate and bovine serum albumin to prevent non-specific binding. See column 11, lines 1-11.

It would have been obvious to one of ordinary skill in the art to have provide the blocking strip and conjugate strip between the collection strip and assay strip as taught by Schlipfenbacher ('486) because Schlipfenbacher ('486) expressly teaches providing the strips as an alternative to merely having corresponding separate zones of a single strip (see Fig. 1 vs. Fig. 2). With respect to the recitation of a non-absorbing sample collection strip, May teaches the same materials as those disclosed in the specification, therefore, the sample absorbing strip of May is seen to have the same inherent characteristics as that of the instant claims. With respect to the recitation of a planar flow communication, May teaches lateral flow and thus it is seen to be the same with planar flow.

*Response to Arguments*

10. Applicant's arguments filed 31 October 2007 have been fully considered and they are partially persuasive.

**35 USC 112, 2<sup>nd</sup> paragraph**

Applicant argues that in light of the amendment to claim 57, claims 57-59 are no longer indefinite. However, the amendment still renders the claims indefinite because they do not have a positive limitation on the structure of the device nor do they specifically recite the reagents that may be present on the device. These claims are nothing more than the intended use of the device and are not given patentable weight.

**35 USC 103(a) May in view of Schlipfenbacher**

Applicant argues that May in view of Schlipfenbacher fail to disclose or suggest an apparatus for collection and lateral flow chromatography of oral fluid that includes a blocking strip, which is impregnated with at least one blocking reagent that reduces non-specific binding on the lateral chromatography strip.

This argument is not persuasive. May teaches all of the limitations of the instant claim including a non-absorbing sample receiving capillary matrix, a lateral flow communication between the sample matrix and the chromatography matrix.

Schlipfenbacher teaches a blocking strip placed between the sample receiving matrix and the conjugate matrix. Schlipfenbacher teaches that the blocking strip comprises buffers and reagents such as BSA, exactly as recited in claim 54, therefore, the blocking



strip of Schlipfenbacher is seen to have the same inherent characteristics as the blocking strip of the instant claims.

Applicant argues that May does not teach applying a blocking agent to any portion of the lateral flow strip because May is not concerned with non-specific binding to the lateral flow chromatography strip as in the claimed invention.

This argument is not persuasive. May teaches throughout its specification and specifically at column 6, lines 45-57, "following the application of the antibody to the detection zone, the remainder of the porous solid phase material should be treated to block any remaining binding sites elsewhere. Blocking can be achieved by treatment with protein (e.g. bovine serum albumin or milk protein), or with polyvinylalcohol or ethanolamine." See also column 10, lines 29-39. Clearly, May teaches the blocking, to prevent non specific binding, the lateral flow chromatography strip. May differs in that the buffers and/or blocking agents are not disposed on a separate strip located between the sample receiving pad and the test strip. However, Schlipfenbacher teaches such a buffer strip. Therefore, it would have been obvious for one of ordinary skill in the art to provide the blocking strip and conjugate strip between the collection strip and assay strip as taught by Schlipfenbacher because this would have been a mere functionally equivalent means for providing reagents to a test strip.

Applicant argues that the material that comprises the sample application of Schlipfenbacher is different from that of the instant invention. This argument is not

persuasive. The non-absorbing capillary matrix is taught by May as discussed above. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Each and every limitation of the claims are taught by May and Schlipfenbacher as well as the motivation for combining these references.

**35 USC 103(a) - Moorman in view of Ching**

The rejection of claims 1, 53-55, 57-58, 60-65 and 67-71 as being unpatentable over Moorman in view of Ching is withdrawn in light of the amendments to the claims and the arguments presented 31 October 2007.

The rejection of claim 59 over Moorman in view of Ziegelmaier is withdrawn in light of the amendments to the claims and the arguments presented 31 October 2007.

**35 USC 103(a) - Kremer in view of Sangha and de Zoeten**

The rejection of claims 1, 53, 55, 57, 58, 60, 61 and 63-71 is withdrawn in light of the amendments to the claims and the arguments presented 31 October 2007.

The rejection of claim 62 is withdrawn in light of the amendments to the claims and the arguments presented 31 October 2007.

**Double Patenting**


The non-statutory double patenting rejection of the claims is withdrawn in light of the amendments to the claims of application number 09/973,956.

*Conclusion*

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641 1/4/08